

Please replace the paragraph on page 8, lines 23-24, with the following paragraph:

B2 FIG. 4 is a top view of an exemplary housing assembly for the assay test strip of FIGs. 1A and 1B;

Please replace the paragraph on page 23, lines 10-16, with the following paragraph:

B3 A preferred embodiment is an immunoassay test strip that includes a membrane system that defines a liquid flow pathway. An exemplary immunoassay test strip provided herein is shown in FIGs. 1A and 1B. The test strip is described in detail in EXAMPLE 1. This test strip is provided for purposes of exemplification of the methods and systems provided herein and is not intended to limit the application to immunoassay test strip devices.

Please replace the paragraph on page 24, lines 14-18, with the following paragraph:

B4 The test strip optionally may be contained within a housing for insertion into the reflectance reader. The housing may be made of plastic or other inert material that does not interfere with the assay procedure. An exemplary assay device, including a test strip and housing assembly is shown in FIGs. 2A-5.

Please replace the paragraph beginning on page 24, line 29, through page 25, line 18, with the following paragraph:

B5 In a particular embodiment, Code 39 is used. An example bar code is shown in FIG. 25. The bar code is made up of 11 alphanumerics, including 2 alphabetic and 9 numeric characters. The first and last characters are asterisks (*), as is standard in the Code 39 system. The lot number is stored as 1 alpha and 4 numeric codes so that product complaints or questions can be traced to a particular lot number. In the exemplified embodiment, the first character represents the month of production, the second is a digit representing the year

U.S.S.N 09/717,478
Anderson et al.
PRELIMINARY AMENDMENT

B5
of production and the last three are an index value indicating the lot number. Thus, the lot number "A8001" represents the first device in a lot produced in January, 1998. The next two characters ("01") represent the identity of the analyte as 2 numerics (00-99). This permits the use of up to 100 different analytes with the system. The reflectance intensity value (00-99) is stored as the next two numeric characters ("01"). The intensity value sets the reference threshold for which controls and patient samples can be compared. This eliminates the need to run liquid reference samples on a daily basis. FIGs. 2A, 2B, and 3 depict assay devices that optionally include bar codes, 216 and 316, respectively. Finally, the cassette expiration date is stored as 1 alpha and 1 numeric code to prevent the use of expired devices. In the example given, an expiration code of "A9" represents an expiration date of January, 1999.

Please replace the paragraph on page 29, lines 20-28, with the following paragraph:

B4
A volume of the test sample is then delivered to the test strip (FIGs. 1A and 1B) using any known means for transporting a biological sample, for example, a standard plastic pipet. Any analyte in the sample binds to the labeled antibody, and the resulting complex migrates along the test strip. Alternatively, the sample may be pre-mixed with the labeled conjugate prior to applying the mixture to the test strip. When the labeled antibody-analyte complex encounters a detection zone of the test strip, the immobilized antibody therein binds the complex to form a sandwich complex, thereby forming a colored stripe.

Please replace the paragraph on page 37, lines 12-18, with the following paragraph:

B7
As can be seen, the actuator arm 1004, the actuator spring 1002, the stepper motor 802, the reader head 706, the reader head mounting bracket 1204, and mechanisms used for supporting and scanning the reader head 706

U.S.S.N 09/717,478
Anderson et al.
PRELIMINARY AMENDMENT

B7 are designed so that the test strip **100** in the device **200** is positioned within 0.010 inches of the aperture **1108** of the reader head. Any design suitable to effect such can be employed with the present embodiment.

Please replace the paragraph on page 44, lines 19-26, with the following paragraph:

B8 At the fiberoptic conductor ends **1902, 1904, 1906**, each fiberoptic fiber (or conductor) has a longitudinal axis that is normal to the plane at the upper surface of the bar code or test strip. As a result, light emitted from the fiberoptic conductor ends **1902** and **1904** is directed in a direction substantially normal to this surface plane. The fiberoptic fibers in each of the three groups are arranged along with fiberoptic fibers from the remaining groups in a sigmoidal (or "S"-like) pattern with three columns of thirteen fibers each.

Please replace the paragraph on page 46, lines 8-15, with the following paragraph:

B9 After being positioned above the housing, the reader head **706** is moved (scanned) across the bar code and/or test strip by the stepper motor under the control of the control circuit to allow the reader head **706** to scan the exposed surface of the bar code and/or assay test strip (including the detection and control zones through the test window **214** in the immunoassay device). As stated above, in a preferred embodiment, the distance between reader head **706** and the bar code or assay test strip **100** is approximately 0.010".

Please replace the paragraph beginning on page 64, line 28, through page 65, line 13, with the following paragraph:

B10 The test strip **100** includes a membrane system including three components: a porous or bibulous member **102**; a conjugate pad **108**; and an absorbent pad **110**. The membrane system may be mounted on a substrate or backing **112**, with the conjugate pad **108** and the absorbent pad **110** slightly

U.S.S.N 09/717,478
Anderson et al.
PRELIMINARY AMENDMENT

BiD overlapping the porous or bibulous member 102, which is interposed thereinbetween. As can be seen in Figures 1A and 1B, the conjugate pad 108 overlaps the porous or bibulous member 102 so that a fluid sample placed onto the conjugate pad 108 is communicated from the conjugate pad 108 to the porous or bibulous member 102. Similarly, the absorbent pad 110 overlaps with the porous or bibulous member 102 so that fluid samples introduced into the porous or bibulous member 102 from the conjugate pad 108 can then be transmitted to the absorbent pad 110. Thus, the conjugate pad 108, the absorbent pad 110 and the porous or bibulous member 102 are all in fluid communication with one another, making any fluid sample placed on the conjugate pad 108 able to propagate through the conjugate pad 108 to the porous or bibulous member 102 and then to the absorbent pad 110.

Please replace the paragraphs beginning on page 66, line 10, through page 67, line 6, with the following paragraphs:

The membrane system may also include an absorbent pad 110, which is also in fluid communication with the porous or bibulous member, and which serves to draw liquid continuously through the device. The absorbent strip may be made of a material such as cellulose paper or other material known to those of skill in the art.

Bi1 Referring to FIG. 2A, which depicts an exemplary immunoassay device, including a test strip and housing assembly 200, the housing 202 generally surrounds the test strip 100 (FIGs. 1A and 1B) and includes an opening through which test sample is applied 204, as well as an aperture above the detection and control zones 206 that permits measurement of the amount of label by the reader, which is correlated with the amount of analyte in the test sample. The housing 202 includes at its upper surface 208 a fattened end 210, used for gripping the housing 202, an application window 204 (or sample window) through which a sample is applied to a conjugate pad 108 of an immunoassay test strip within the housing 202. The housing 202 also includes a test window